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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. **FILING DATE** APPLICATION NO. R 01/06/99 LORIA 09/225,499 **EXAMINER** Г HM22/0426 GOLDBERG, J BRIAN P. O SHAUGHNESSY, ESQ. BURNS, DOANE, SWECKER & MATHIS, L.L.P. ART UNIT PAPER NUMBER P.O. BOX 1404 1614 ALEXANDRIA VA 22313-1404 **DATE MAILED:** 04/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

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Application No. 09/225,499 App cant(s)

Loria

Examiner

Jerome D. Goldberg

Group Art Unit 1614



X Responsive to communication(s) filed on Dec 30, 1999	<u> </u>
☑ This action is FINAL.	
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).	
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
☐ Claim(s)	is/are allowed.
X Claim(s) 15-20	is/are rejected.
☐ Claim(s)	
☐ Claims a	
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.	
☐ The drawing(s) filed on is/are objected to	
☐ The proposed drawing correction, filed on	is Lapproved Ldisapproved.
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been	
☐ received. ☐ received in Application No. (Series Code/Serial Number)	
☐ received in Application No. (Series Code/Serial Number) ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).	
*Certified copies not received:	
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s) Notice of References Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)	
☐ Interview Summary, PTO-413	
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	
□ Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FO	OLLOWING PAGES

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Claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific tumors disclosed on page 5, lines 6-14, does not reasonably provide enablement for the term "tumor proliferation". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "tumor proliferation: in claims 15-20 lacks clear exemplary support in the specification as filed.

1. The cancer therapy art remains highly unpredictable, and no example exists for efficacy of a singe product against tumors generally. Therefore, based on the predictable nature of the invention and state of the prior art, the lack of guidance and working examples, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

(See claim 1 last two lines of the parent patent).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg, whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday from 9:00 a.m. to 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintinis, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

J. Goldberg:jmr

April 13, 2000

JEROMÉ D. POLDBERG PRIMATY EXAMINER

GROUP 1200